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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,630	03/09/2004	Roger Dillard Massengale	IFLOW.084C1	2791

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EXAMINER	
FIDEI, DAVID	

ART UNIT	PAPER NUMBER
3728	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,630	MASSENGALE ET AL.	
	Examiner	Art Unit	
	David T. Fidei	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Request for Information

1. An article by Home Care Magazine reported on October 1, 1999 I-Flow Corporation obtained clearance from the FDA to market its new nerve block infusion kit. The article goes on to report the kit is administered by an anesthesiologist and provides a continuous infusion of a local anesthetic near a nerve for pain management for orthopedic and general surgery, see the second paragraph of the Briefly Noted article cited from HomeCare Magazine Staff, October 1, 1999.

However, nothing is provided by applicant (I-Flow Corporation in PCT/US02/11986) indicating the presence or content of such a kit. Applicant should provide the examiner with a disclosure of the contents of this kit, its use, how the components were packaged and distributed or any other information material to the request for consideration by the examiner. 35 C.F.R. 1.56 provides the basis for this request.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiss et al (Patent no. 3,650,393). As to claim 1, a pain management kit for performing a nerve block procedure, comprising; a container 11, 13 including a peripheral surface; a cover 27 releasably secured to said peripheral surface of said container said container and said cover defining a sterile space therebetween, see col. 2, lines 49-50; and a plurality of sterile medical items 20 disposed within said sterile space, said container and cover being configured such that said medical items remain sterile at least until said cover is removed from said container; wherein

said plurality of medical items comprise supplies to create a sterile field surrounding a desired pierce site of a patient see col. 3, lines 49-66, supplies to locally anesthetize said pierce site and supplies to perform a continuous nerve block of a desired block site of said patient, see col. 2, lines 65 to col. 3, line 15.

As to claim 2, the sterile field supplies are arranged separately from said local anesthetic supplies and said continuous nerve block supplies, see figure 5.

As to claim 3, the kit additionally includes what can be characterized as a sterile field tray 18 and a main tray 19 disposed within said sterile space, note figure 3, wherein said sterile field supplies are arranged within said sterile field tray and said local anesthetic supplies and said continuous nerve block supplies are arranged within said main tray.

As to claim 6, a method of using the pain management kit is contemplated by Reiss et al where one removes the cover 14 from said container to expose said plurality of medical items as in figure 5, creating a sterile field about said pierce site of a patient using the sterile field supplies described by the disclosure of prep swabs 30 or towel 33a, see col. 3, lines 49-66; and performing a continuous nerve block procedure on a nerve bundle using said continuous nerve block supplies described col. 2, lines 67-68.

As to claim 7, a pain management kit for performing a nerve block procedure is disclosed comprising; a container 11, 13 including a peripheral surface; a cover 27 releasably secured to said peripheral surface of said container, said container and said cover defining a sterile space therebetween; at least one tray 18 or 19 positioned within said sterile space; a plurality of sterile medical items 20 disposed within said at least one tray; a sterile wrap 14 including a central portion and a peripheral portion surrounding said central portion, said central portion of said sterile wrap interposed between said at least one tray and said container, said peripheral portion of said sterile wrap folded to cover said plurality of medical items see figure 3; wherein said plurality of medical items comprise supplies to create a sterile field surrounding a desired pierce site of a patient see col. 3, lines 49-66, supplies to locally anesthetize said pierce site and supplies to perform a continuous nerve block of a desired block site of said patient see col. 2, lines 65 to col. 3, line 15.

As to claim 8, the sterile field supplies are arranged separately from said local anesthetic supplies and said continuous nerve block supplies, see figure 5.

As to claim 9, at least one tray comprises a sterile field tray 18 and a main tray 19, wherein said sterile field supplies are arranged within said sterile field tray and said local anesthetic supplies and said continuous nerve block supplies are arranged within said main tray.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hultberg et al (Patent no. 3,770,119) in view of Reiss et al. Hultberg et al discloses a medical procedure kit in the embodiment of figure 6 where there is disclosed a tray 10 with auxiliary trays 26, 28. A cover 14 is disclosed in combination with a wrap 18a including a central portion and a peripheral portion surrounding said central portion, said central portion of said sterile wrap interposed between said at least one tray and said container, said peripheral portion of said sterile wrap folded to cover said plurality of medical items see figures 6 and 8. Hultberg et al col. 1, lines 7 and 8 states the trays are sterile and may be used for spinal anesthesia. The difference between claims 1, 7 and the disclosure of Hultberg et al resides in the said plurality of medical items comprise supplies to create a sterile field surrounding a desired pierce site of a patient along with supplies to locally anesthetize said pierce site and supplies to perform a continuous nerve block of a desired block site of said patient. Hultberg generally states the trays are provided with supplies necessary to perform a medical procedure.

Reiss et al discloses that it is known to one skilled in the art of administering anesthesia to provide medical kits with a plurality of medical items comprise supplies to create a sterile field surrounding a desired pierce site of a patient see col. 3, lines 49-66, along with supplies to locally anesthetize said pierce site and supplies to perform a continuous nerve block of a desired block site of said patient, see col. 2, lines 65 to col. 3, line 15. It would have been obvious to one of ordinary skill in the art to modify the tray of Hultberg et al by providing supplies to locally anesthetize said pierce site and supplies to perform a continuous nerve block of a desired block site of said patient as suggested by Reiss et al, in order to provide a complete package with the necessary instruments required for the procedure.

As to claims 2 and 8, Reiss et al teaches arranging the sterile field supplies separately from said local anesthetic supplies and said continuous nerve block supplies, see figure 5.

As to claims 3 and 9, Reiss et al additionally teaches includes what can be characterized as a sterile field tray 18 arranged on top of a main tray 19 disposed within said sterile space, note figure 3. To apply the same principle to Hultberg et al where trays 26, 28 contain the sterile field supplies are arranged within a sterile field tray and said local anesthetic supplies and said continuous nerve block supplies are arranged within a main tray 10 would have followed from the teachings of Reiss et al.

As to claims 4 and 10, the main tray 10 of Reiss et al defines an internal space with the auxiliary trays 26, 28 disposed within said internal space.

As to claims 5 and 10, main tray 10 includes what can be considered at least one stop surface 36 in figure 6 defining a first compartment. The stop surface being configured to substantially secure said sterile field tray within said first compartment

As to claim 6, the method of using the kit is embodied in the combination as discussed with reference to the previous rejection.

REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION

6. "In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant 's or patent owner 's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)", see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

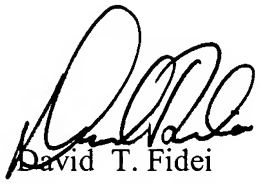
If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner 's action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematureness of final rejection or admission of subsequent amendments do not necessarily reflect present practice. "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)" (emphasis mine), see MPEP 706.07(a).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David T. Fidei
Primary Examiner
Art Unit 3728

dtf
January 10, 2005